PRESS RELEASE
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ANNEXIN RECEIVES APPROVAL FOR PHASE 2A STUDY IN DIABETIC RETINOPATHY AND RVO

Annexin Pharmaceuticals AB has received approval from the UK Medicines and Healthcare products Regulatory Agency (MHRA) to start a clinical Proof of Concept phase 2a study with the drug candidate ANXV in the eye disease diabetic retinopathy (DR). As a complement to the recently completed Phase 2a study in retinal vein occlusion (RVO), and as part of the preparation work for an upcoming Phase 2b study, patients with newly diagnosed RVO will also be included. The aim is to evaluate a shorter treatment cycle than before, which has been inquired by some potential licensees. The first patients are expected to be treated in the coming month, and initial data are expected about three months later and thereafter on an ongoing basis.

Diabetic retinopathy is a serious eye disease that occurs in patients with type 1 and type 2 diabetes and can lead to significant visual impairment and blindness. The disease causes vascular changes and swelling of the retina similar to that which occurs in patients with RVO, and the standard treatment with repeated drug injections into the eye is similar.

"Diabetic retinopathy is basically a vascular disease caused by damage to small blood vessels in the retina. Our previous promising Phase 2a data in RVO strengthen our expectation that ANXV may also be effective in diabetic retinopathy – a serious condition where there is a high demand for new treatment options. The study as a whole is of great importance as, in addition to broadening the potential area of use and thereby increasing the future market for ANXV, we can get answers to questions that arise in our ongoing partnership discussions", says Anders Haegerstrand, CEO of Annexin Pharmaceuticals.

The Phase 2a study will be conducted at The Retina Clinic in London, UK, with Professor Paulo-Eduardo Stanga as Principal Investigator and will include patients with moderate to severe DR and newly diagnosed RVO. The study design means that the first patients in each disease indication are treated for five days with ANXV. Based on results after about one month, decisions are made about the treatment of the next patients within the two indications. The adaptive study design, with evaluation of two indications in parallel at a single clinic, enables the study to be conducted in a time- and cost-effective manner. The study will also provide the company with important information for the preparation of a phase 2b study, which is mainly expected to be conducted by or in collaboration with an industrial partner.

"I have reviewed the Phase 2a data in RVO and ANXV appears as a safe and promising drug candidate for the treatment of RVO and DR. I believe we will be able to further document safety and tolerability, and capture potential early and beneficial effects in both diseases with the benefit of our clinical and research experience and state-of-art functional and imaging equipment for assessing the retina", says Professor Paulo-Eduardo Stanga in a comment.

"The effects we have seen in patients with RVO are in many cases so rapid that we now want to investigate whether we can treat fewer days with similar results, especially a reduction from 5 to 3 days. The clinic we collaborate with has access to very advanced technology and is considered to have many patients who may be suitable to be included in the study. We therefore expect patient recruitment to proceed relatively quickly and look forward to important results from the study already before the end of the year," concludes Anders Haegerstrand.

About the study
Annexin's phase 2a/proof of concept study has a so-called adaptive design and includes patients with diabetic retinopathy of the non-proliferative type where there is an impact on retinal blood vessels and blood supply, but where the patient is not yet in need of so-called anti-VEGF therapy. The study also includes patients who have recently suffered RVO, but do not require immediate anti-VEGF treatment. It is an open-label study without a placebo group or comparison with another drug. The study is being conducted at The Retina Clinic in London, UK, with Professor Paulo-Eduardo Stanga as principal investigator and is planned to initially include three patients with diabetic retinopathy, as well as three patients with newly diagnosed RVO. These are treated with ANXV for five days and followed up with detailed tests for 30 days, after which decisions are made regarding further patient recruitment. All patients are followed less intensively for an additional 90 days. Evaluation is made of safety, tolerability and any signals of effect that may be related to ANXV. In addition to standardized tests of best corrected visual acuity (BCVA), the degree of diabetes-caused retinal damage, swelling of the retina and the need for anti-VEGF injections, objective functional tests and analyses of blood flow and vascular changes are performed. The first patient is expected to be treated in the third quarter of 2025 and initial data is expected approximately three months later and thereafter on an ongoing basis.

About diabetic retinopathy (DR)
Diabetic retinopathy is a serious eye disease and one of the leading causes of vision loss and blindness in people with diabetes. The disease occurs when high blood sugar levels damage the small blood vessels in the retina, leading to leakage, lack of oxygen and the formation of new, fragile blood vessels. Today's treatments include anti-VEGF injections, laser treatment, and surgery, but these are often costly, require repeated interventions, and do not always provide sufficient effect. There is therefore a great need for new, more effective and long-lasting treatment options. Globally, it is estimated that over 100 million people are living with diabetic retinopathy, and with an increasing prevalence of diabetes, the number is expected to rise sharply.

About Retinal Vein Occlusion (RVO)
RVO is a vascular disease of the eye in which blood flow in the retinal veins is blocked. The disease often leads to severe visual impairment or blindness and the need for long-term treatment. Today's standard treatment for RVO consists of injections directly into the eye, usually once a month, but has no effect on the blockage of blood vessels that is the cause of RVO. Sources put the prevalence of RVO in the world at between 16 and 28 million people being affected.

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About Annexin Pharmaceuticals AB
Annexin Pharmaceuticals AB is a leading biotechnology company in the Annexin A5 field for the treatment of various diseases. The company's biological drug candidate ANXV – a human recombinant protein, Annexin A5 – is primarily intended for treatment of patients with injuries and inflammation of the blood vessels, but also for cancer. The company has an extensive patent portfolio for the treatment of diseases with Annexin A5 and for production of Annexin A5.
The Company is based in Stockholm, Sweden and listed on Nasdaq First North Growth Market, under the ticker ANNX. Redeye is the company´s Certified Adviser.

Attachments
Annexin receives approval for Phase 2a study in diabetic retinopathy and RVO